

### REMARKS

Claims 32-69 are presented for consideration by the Examiner. The claims have been considered in response to the rejections and remarks in the Office Action mailed March 12, 2003, and every ground of rejection has been addressed.

In the Office Action, claim 41 was rejected under 35 U.S.C. §102(b) as being clearly anticipated by German Patent No. 299 01 611 U1 to Aesculap (Aesculap). Claims 32-35, 37-40, 48 and 51 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by Japanese patent 9-122160 A to Kyocera (Kyocera). Claims 36, 41, 44-47, 49, and 50 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kyocera. Claims 42-43 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent No. 4,834,757 to Brantigan (Brantigan).

New claims 52-69 have been added. The subject matter of new claims 52-69 is supported in the disclosure and is therefore not new matter. Support for the new claims can be found in the following locations in the disclosure:

claim 52 is supported, inter alia, on page 21, lines 19-20;

claims 53, 58 and 61 are supported, inter alia, on page 15, lines 8-12, and FIG. 3;

claim 54, 59, and 62 are supported, inter alia, on page 19, lines 5-20, and FIG. 7;

claim 55 is supported, inter alia, on page 19, lines 5-20, and FIG. 7;

claim 56 is supported, inter alia, on page 19, lines 5-20, and FIG. 7;

claim 57 is supported, inter alia, on page 20, lines 1-5, and FIG. 7;

claims 60 and 63 are supported, inter alia, on page 19, line 5 to page 20, line 5, and FIG. 7;

claims 64 and 67 are supported, inter alia, on page 13, lines 1-4;

claim 65 is supported, inter alia, in original claim 9;

claim 66 is supported, inter alia, on page 22, line 22 to page 23, line 4; and

claims 68 and 69 are supported, inter alia, in original claim 41, and FIG. 7, as well as the additional locations discussed below.

1. OBJECTIONS TO THE DISCLOSURE ARE TREATED

An objection was made to the abstract in the Office Action for inclusion of legal phraseology including the word "said." A replacement abstract is attached hereto, in which the word "said" is replaced with the word "the." The replacement abstract is submitted on a separate sheet in accordance with 37 C.F.R. § 1.72. Accordingly, the abstract is believed to be proper and it is

respectfully requested that the objection to the abstract be withdrawn.

The Office Action also required that the Applicants specifically point out the support in the original disclosure for each of the claims added since the filing of the parent application (serial no. 09/592,072). The support in the original disclosure for each of the added claims is specifically pointed out below.

Regarding claim 44, the subject matter of claim 44 is supported in the disclosure, inter alia, on page 17, lines 5-11, and FIGS. 8B and 9, and is therefore not new matter.

Regarding claim 45, the subject matter of claim 45 is supported in the disclosure, inter alia, on page 17, lines 11-14, and is therefore not new matter.

Regarding claim 46, the subject matter of claim 46 is supported in the disclosure, inter alia, on page 17, lines 14-17, and is therefore not new matter.

Regarding claim 47, the subject matter of claim 47 is supported in the disclosure, inter alia, on page 18, lines 6-18, and is therefore not new matter.

Regarding claim 48, the subject matter of claim 48 is supported in the disclosure, inter alia, on page 18, lines 19-23, and is therefore not new matter.

Regarding claim 49, the subject matter of claim 49 is supported in the disclosure, inter alia, on page 19, lines 1-4, and is therefore not new matter.

Regarding claim 50, the subject matter of claim 50 is supported in the disclosure, inter alia, on page 21, lines 1-3, and is therefore not new matter.

Regarding claim 51, the subject matter of claim 51 is supported in the disclosure, inter alia, on page 21, lines 3-10, and is therefore not new matter.

2. REJECTIONS OF CLAIMS UNDER 35 U.S.C. § 112 ARE TREATED

Claims 32-38 and 42-51 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention due to the spelling of "anulus" in claim 32, line 3, for example. Applicants respectfully traverse this rejection. Enclosed herewith is a print from a dictionary (dictionary.com, citing WordNet® 1.6, © 1997 Princeton University) showing the word "anulus" spelled the same way Applicants spelled the word in the present application. Applicants respectfully submit that such spelling of "anulus" is proper, and as shown in the attached definition, "anulus" is synonymous with "annulus." Accordingly, Applicants respectfully request that the rejection be withdrawn.

3. REJECTIONS OF CLAIMS UNDER 35 U.S.C. §§ 102 AND 103 ARE TREATED

Regarding the rejection of the claims under 35 U.S.C. §§ 102 and 103, applicants' counsel has carefully studied the reasoning for the rejection provided in the Office Action, together with the three (3) prior art references relied upon. Applicants respectfully submit in good faith that certain aspects of the invention are unanticipated, nonobvious and allowable. Additional limitations have been incorporated into independent claims 41 and 42, without prejudice to any future submission of the original claims in another application, which are believed to render said claims allowable.

Regarding claims 32, 37 and 39, each of these independent claims require the step of applying compression to posterior portions of the adjacent vertebral bodies. The Office Action indicates that this step is anticipated by Kyocera. However, after analyzing a translation of the Kyocera reference, a copy of which is submitted concurrently herewith in a Supplemental Information Disclosure Statement, it is clear that Kyocera does not disclose this step. The plate B disclosed in FIG. 2 of the Kyocera reference is merely used to hold the vertebrae in place with respect to each other, and not to apply compression to posterior portions of the adjacent vertebral bodies. On page 6 of the translation, lines 4-6, the Kyocera reference indicates that "a spinous process plate B is used together for the instability due to

anteflexion or retroflexion motion to restrict the relative motion of the vertebral body F positioned above and below the interbody J." Also, on page 4, lines 23-26, the Kyocera reference states that "for the instability caused by precurvating and recurvating motions, a spinal plate is used together to restrict the relative motions of upper and lower vertebrae of the interbody." Thus, for example, if the spine is bent backwards the plate B will form a bridge to prevent the vertebrae from compressing together. If the spine is bent forward, the plate B would prevent the vertebrae from separating further apart. However, nowhere does the Kyocera reference indicate that the plate B is used to apply compression to posterior portions of the adjacent vertebral bodies. The step of applying pressure, as shown in FIGS. 8D and 9 of the present disclosure, is used to load the bone graft in compression and restore sagittal alignment.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegall Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since the Kyocera and other references do not disclose all the subject matter of claims 32, 37 and 39, those claims are not anticipated.

Furthermore, the Kyocera and other references of record do not suggest the concept of applying compression to posterior portions

of the adjacent vertebral bodies. Since the prior art references of record lack a specific supporting teaching of the subject matter claimed in claims 32, 37, and 39, the prior art of record cannot be used to render obvious those claims. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989). Furthermore, there is no motivating suggestion to render the claim obvious that is "clear and particular" as required. Winner International Royalty Corp. v. Wang, No. 53 USPQ.2d 1580 (Fed. Cir. 2000). It would take a retrospective view of the prior art references in light of applicants' discovery, to obtain any of the specific necessary teachings and elements discovered and set forth in the above-identified application, an undertaking which is clearly prohibited by law. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989). Claims 32, 37, and 39 are therefore believed to be allowable, and nonobvious under section 103 as that statute might be applied.

Dependant claims 33-36, 38, 40, and 44-63 depend from claims 32, 37, or 39, or a claim depending from those claims, and are therefore believed to be allowable for at least the reasons given in support of claims 32, 37, and 39.

Regarding independent claim 41, additional subject matter has been added to the claim including " wherein the spacing member comprises an upper surface and a lower surface and a free insertion end, and wherein said spacing member includes a tapered portion such that said spacing member becomes progressively thinner toward

said free insertion end of said spacing member." This subject matter is supported in the disclosure, inter alia, on page 15, lines 8-12, and FIGS. 1-3, and is therefore not new matter.

The Aesculap reference does not disclose a spacing member having a tapered insertion end. Further, Aesculap discloses a device having separable arms 3 that spread the vertebrae apart to receive the spacing member, indicating the use of vertebral spreading to facilitate insertion of the spacing member instead. Moreover, the Kyocera reference does not teach or suggest the tapered insertion end. Accordingly, the Aesculap reference, the Kyocera reference and the other references of record, do not disclose, teach or suggest all of the features now recited in claim 41. Accordingly, claim 41 is believed to be allowable.

Dependant claim 64 depends from claim 41 and is therefore believed to be allowable for at least the reasons given in support of claim 41.

Regarding claim 42, subject matter has been added to the claim including "said trial spacer having sharp edging for clearing away tissue." This subject matter is supported in the disclosure, inter alia, on page 18, lines 16-18, and FIG. 6, and is therefore not new matter.

The trial spacer having sharp edging is not disclosed or suggested by Brantigan. Moreover, column 5, lines 65-68 discloses that "the tapers 19e are preferably about 30 degrees. The rounded



corners 19f of the bevels eliminate sharp corners between the top, bottom and sides of the bevel faces." Thus, Brantigan teaches away from sharp edging. It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Since the subject matter of claim 42 is not disclosed, taught or suggested by the prior art of record, including Brantigan, claim 42 is believed to be allowable.

Dependant claims 65-67 depend from claims 42, or a claim depending from claim 42, and are therefore believed to be allowable for at least the reasons given in support of claim 42.

New claims 68 and 69 are believed to be allowable over all prior art of record. Claim 68 is identical to original claim 41, except that it includes the additional subject matter in part (c), indicated in underline as follows:

(c) attaching a rigid inflexible member to the spacing member, said rigid inflexible member being straight along a majority length thereof, and using said rigid inflexible member for directing and inserting the spacing member along an arcuate insertion path through the incision such that the imaginary arcuate centerline follows said arcuate insertion path during the insertion.

This subject matter is supported in the disclosure, inter alia, on page 19, lines 5-10, page 19, line 23 to page 20 line 10, and FIG. 7, and is therefore not new matter.

Neither the Kyocera reference nor the Aesculap reference disclose the combination of steps in which a spacing member is

inserted into an anulus with the aid of a rigid inflexible member that is straight along a majority length thereof. The Aesculap reference teaches away from such a combination, by requiring a curved, rod-shaped retaining element 36 to use in conjunction with a curvate guide member 1. The Kyocera reference does not even show any type of guiding insertion member. Accordingly, new claims 68-69 are believed to be allowable.

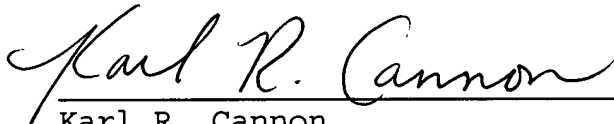
4. CONCLUSION AND AUTHORIZATION OF DEPOSIT ACCOUNT

In view of the foregoing, applicants believe that claims 32-69 are all allowable and the same is respectfully requested. If any impediment to the allowance of these claims remains after entry of this Amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to initiate the same.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 50-0836.

DATED this 12 day of September, 2003.

Respectfully submitted,

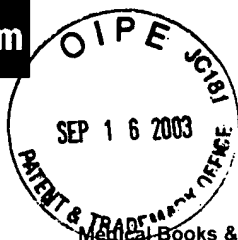


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